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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083

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EXAMINER	
PELLEGRINO, BRIAN E	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,703	BARCLAY ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,8,9,19-22,25,26,38-40,42,74-76,78,102,104,108 and 111-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,8,9,19-22,25,26,38-40,42,74-76,78,102,104,108 and 111-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7/11/05* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/11/05 has been entered.

Claim Objections

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from a canceled claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,9, 19-22,25,26,38-40,74-76,108,111,113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (WO 98/47447) in view of Ragheb et al. (5873904). Dubrul shows (Fig. 4D) a helical coiled stent **50** with radially extending openings **51** illustrated in Fig. 4C, which create open spaces where no portion of the coiled stent body would be. Dubrul also discloses a biologically active agent is coated

on the stent, page 11, lines 5,6. Dubrul additionally discloses the stent is made of metal, page 10, lines 15-18. However, Dubrul fails to disclose a coiled sleeve extending along the helical stent or any specific drugs for use. Ragheb teaches to cover the stent with a sleeve to control release of the agents (col. 4, lines 28-32) and teaches anti-inflammatory drugs can be delivered through the sleeve, col. 4, lines 55-67. Ragheb also teaches the porous sleeve material is a polymer, col. 12, lines 20,21. It would have been obvious to one of ordinary skill in the art to use a sleeve as taught by Ragheb and cover the coiled stent of Dubrul such that it forms a coiled sleeve to control release of the drug. Regarding claims 19-20, Dubrul fails to disclose the use of multiple agents with the sleeve. Ragheb teaches that porous polymers are used for controlling drug release, col. 6, lines 56-60. Ragheb also teaches the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14. It would have been obvious to one of ordinary skill in the art to use a second agent as taught by Ragheb with the stent of Dubrul, such that the device has enhanced capabilities and multiple treatment capabilities. Regarding claim 22, it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before a second is released, since applicant has not disclosed that using any set amount of one over another provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rates and amounts taught by Ragheb or the claimed at least half of first agent in claim(s) 22 because both designs perform the same function of releasing agents into the patient.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (WO 98/47447) in view of Ragheb et al. '904 as applied to claim 40 above, and further in view of Scott et al. (5383928). Dubrul in view of Ragheb et al. is explained supra. However, Dubrul as modified by Ragheb fail to disclose a delay release layer that is biodegradable. Scott et al. teach a polymer sleeve that is biodegradable to control delivery of bioactive drugs from the stent, col. 6, lines 60-68. It would have been obvious to one of ordinary skill in the art to utilize a biodegradable polymer release layer as taught by Scott et al. with the stent of Dubrul as modified by Ragheb in order to provide a stent capable of controlling the release of a drug into a patient's vascular system.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (WO 98/47447) in view of Ragheb et al. '904 as applied to claim 38 above, and further in view of Kropf '849. Dubrul in view of Ragheb et al. is explained supra. However, Dubrul as modified by Ragheb fail to disclose the coiled body having spaced apart turns having gaps and the body having longitudinal side members and cross members. Kropf teaches a coiled stent with spaced apart turns and longitudinal members connected with cross members, Fig. 5. Kropf teaches that the structural design enables the prosthesis to be deployed in a small profile reducing the likelihood of vessel trauma, col. 3, lines 8-13. It would have been obvious to one of ordinary skill in the art to substitute the stent design of Kropf in the stent of Dubrul as modified by Ragheb in order to provide a stent with good flexibility and a small profile for delivery.

Claims 42,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (WO 98/47447) in view of Ragheb et al. '904 as applied to claim 38 above, and further in view of Khosravi '054. Dubrul as modified by Ragheb is explained supra. However, Dubrul in view of Ragheb fail to disclose the porous sleeve is PTFE. Khosravi teaches the sleeve material covering the stent is made of PTFE, col. 5, lines 9,10. It would have been obvious to one of ordinary skill in the art to substitute porous polymers and use PTFE as a sleeve as taught by Khosravi with the stent of Dubrul as modified by Ragheb since it is known to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Claims 102,104,112,114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (WO 98/47447) in view of Ragheb et al. '904 as applied to claims 38 and 74 respectively above, and further in view of Hanson (5399352). Dubrul in view of Ragheb et al. is explained supra. However, Dubrul as modified by Ragheb fail to disclose the sleeve interior being oversized relative to the coiled body or to use NO generators. Hanson teaches that a reservoir (oversized) is used alone to hold drugs, such as NO generators to prevent restenosis in combination with a prosthetic device, col. 5, lines 60-62, col. 6, lines 3-5. Hanson also shows (Fig. 4) the reservoir is oversized **20** for the drug. It would have been obvious to one of ordinary skill in the art to use an oversized reservoir and use an NO generator as taught by Hanson within the sleeve interior holding the stent of Dubrul as modified by Ragheb et al. so that a sufficient or greater amount of drug can be administered to the site and prevent restenosis via an NO generator.

Response to Arguments

Applicant's arguments with respect to claims 38 and 74 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 7am to 4:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino